

WHAT IS CLAIMED IS:

Sub A
1. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than 5 μm , the microparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

or
2. The *method* of Claim 1, wherein the microparticles are sized such that at least 50% of the microparticles are less than 3 μm .

Sub C
3. The vaccine formulation of Claim 1, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

4. The vaccine formulation of Claim 1, wherein the microparticles are formed using a solvent evaporation method.

or
5. The *method* of Claim 1, wherein the antigen comprises a *B. pertussis* antigen.

or
6. The *method* of Claim 1, wherein the microparticles comprise at least 2 subpopulations of microparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.

Sub D
7. A vaccine formulation for oral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than 600nm, the nanoparticles comprising at least one antigen entrapped or encapsulated by a biodegradable polymer.

C *SB* *D*
8. The *method* of Claim 7, wherein the nanoparticles are sized such that at least 50% of the microparticles are less than 500nm.

Sub A4 9. The vaccine formulation of Claim 7, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof.

10. The vaccine formulation of Claim 7, wherein the nanoparticles are formed using a coacervation method.

c 11. ~~The vaccine formulation of Claim 7, wherein the antigen comprises a *B. pertussis* antigen.~~

Sub D1 12. ~~The vaccine formulation of Claim 7, wherein the nanoparticles comprise at least 2 subpopulations of nanoparticles, each subpopulation comprising a different antigen entrapped or encapsulated by a biodegradable polymer.~~

Sub A5 13. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of microparticles sized such that at least 50% of the microparticles are less than $5 \mu\text{m}$, the microparticles comprising at least one *B. pertussis* antigen entrapped or encapsulated by a biodegradable polymer.

14. The method of Claim 13, where the microparticles are sized such that at least 50% of the microparticles are less than $3 \mu\text{m}$.

Sub A6 15. The method of Claim 13, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid and enantiomers thereof and wherein the microparticles are formed using a solvent evaporation method.

16. The method of Claim 13, wherein the at least one *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), pertactin and fimbriae and combinations thereof.

Sub A7 17. A method of inducing a protective immune response against *B. pertussis*, comprising orally administering to a subject a pharmaceutically effective amount of nanoparticles sized such that at least 50% of the nanoparticles are less than

600nm, the nanoparticles comprising at least one *B. pertussis* antigen entrapped or encapsulated by a biodegradable polymer.

18. The method of Claim 17, where the nanoparticles are sized such that at least 50% of the ^N microparticles are less than 500nm.

19. The method of Claim 17, wherein the biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof and wherein the nanoparticles are formed using a coacervation method.

20. The method of Claim 17, wherein the at least one *B. pertussis* antigen is selected from the group consisting of inactivated pertussis toxin (PTd), filamentous hemagglutinin (FHA), pertactin and fimbriae and combinations thereof.

add
B5

add
D1